

6-20-01

June 20, 2001

MEMORANDUM:

SUBJECT: Tolerance Reassessment Eligibility Document (TRED) of **Ethephon (PC Code 099801)**: Product and Residue Chemistry Considerations. **DP Barcodes #** D280985, D283022, & D283027. **Reregistration Case 0382. MRID No. None.**

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Registration Division (7505C)

Attached are the updated product chemistry and residue chemistry considerations for the tolerance reassessment of the plant growth regulator ethephon. This serves to update the Ethephon Product and Residue Chemistry Chapters of 8/30/94 which were written before FQPA. A number of residue chemistry studies were submitted in response to the Registration Standard. These studies have been reviewed separately and conclusions included in the attached updated Product Chemistry and Residue Chemistry Chapters.

EXECUTIVE SUMMARY:

- All pertinent data requirements are satisfied except GLNs 830.6313 and 830.7050 for the Aventis CropScience 71.3% formulation intermediate (FI). The registrant must submit the data required in the attached data summary table and either certify that the suppliers of beginning materials and the manufacturing process for the ethephon manufacturing-use product (MP) have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package. HED has no objections to the reregistration of ethephon with respect to product chemistry data requirements if this data is submitted for review.
- The Agency reviewed the new proposed plant and animal enforcement methods and concluded that in order for the proposed methods to be considered adequate for enforcement purposes, they must undergo a successful independent laboratory validation (ILV) as described in PR Notice 88-5 (7/15/88) followed by a successful method validation by the Agency. The ILV has been reviewed and found adequate by HED (T. Morton, 5/2/02, D280666). The method will be forwarded to the Agency laboratory for method validation.
- Analytical reference standards must be supplied as requested by the EPA National Pesticide Standards Repository for ethephon.

cc : Chem F, Chron F. Morton
RDI:Team: 5/15/02; ChemSAC: 5/22/02; SVH:6/20/02
TM, Thurston Morton, Rm. 816D CM2, 305-6691, mail code 7509C

ETHEPHON

TOLERANCE REASSESSMENT ELIGIBILITY DOCUMENT:

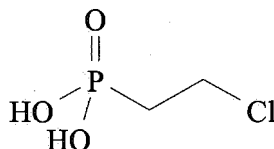
PRODUCT CHEMISTRY CONSIDERATIONS

(Shaughnessy No. 099801; Case No. 0382)

DP Barcode Nos. D280985, D283022, & D283027

DESCRIPTION OF CHEMICAL

Ethephon [(2-chloroethyl) phosphonic acid] is a plant growth regulator that promotes fruit ripening, abscission, flower induction, and other responses by releasing ethylene gas, a natural plant hormone.



Empirical Formula:	C ₂ H ₆ ClO ₃ P
Molecular Weight:	144.5
CAS Registry No.:	16672-87-0
Shaughnessy No.:	099801

IDENTIFICATION OF ACTIVE INGREDIENT

Pure ethephon is a white waxy solid with a melting point of 74-75 C. Ethephon is very soluble in water, alcohol, acetone, and propylene glycol, only slightly soluble in aromatic solvents such as benzene and toluene, and insoluble in kerosene and diesel oil. The vapor pressure of ethephon is $<1 \times 10^{-7}$ mm Hg at 25 C. The octanol/water partition coefficient (p) is $<0.603 \pm 0.0006$ at 25 C. The dissociation constant for ethephon is: $K_1 = 3.16 \times 10^{-3}$ and $K_2 = 6.31 \times 10^{-8}$ at 25 C.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 1/29/02 identified a single ethephon MP registered to Aventis CropScience, a 71.3% FI; (EPA Reg. No. 264-511). The 71.3% FI, which is manufactured by an integrated process, was registered 12/6/90. An 87% technical (T; EPA Reg. No. 264-276), for which data were reviewed in the Ethephon Reregistration Standard dated 4/19/88 and the Ethephon Guidance Document dated 9/88, was canceled 1/22/91. Only the Aventis CropScience 71.3% FI (EPA Reg. No. 264-511) is subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Ethephon Guidance Document dated 9/88 required that all new product chemistry data be submitted in support of the reregistration of ethephon. The Ethephon Reregistration Standard Update dated 4/23/91 summarized data submitted by Rhone-Poulenc for the 71.3% FI which had been reviewed by the Registration Division. The Update concluded that data reflecting preliminary analysis of the 71.3% FI were not representative of the ethephon TGAI because additional impurities might be present in an isolated technical grade active ingredient (TGAI) which would not be detected in the more dilute FI. The Update required additional data concerning GLN 830.1700 and conditional data concerning GLNs 830.1550, 1750, and 1800 dependent on the determination of different impurity levels or the detection of additional impurities in the required preliminary analysis. Additional data were also required pertaining to TGAI requirements for GLNs 830.6303 and 830.6304; data pertaining to GLNs 830.6313 and 830.6317 were outstanding.

Following the Update, the registrant submitted arguments for their use of the 71.3% FI in preliminary analysis, stating that a technical product is not isolated in the current manufacturing process and that the 71.3% FI is the practical equivalent of the TGAI. HED accepted this justification (CBRS No. 8501, D168263, dated 10/18/91, by P. Deschamp), thus resolving TGAI requirements for GLNs 830.6303 and 830.6304. HED reviewed (B. Cropp-Kohlligian, D192173, 3/29/95) the analytical methods used in preliminary analysis of the 71.3% FI and determined the limits of detection (LODs) were sufficiently low to fulfill data requirements for the TGAI.

The current status of the product chemistry data requirements for the Aventis CropScience product is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

All pertinent data requirements are satisfied except GLNs 830.6313 and 830.7050 for the Aventis CropScience 71.3% FI. The registrant must submit the data required in the attached data summary table and either certify that the suppliers of beginning materials and the manufacturing process for the ethephon MP have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package. HED has no objections to the reregistration of ethephon with respect to product chemistry data requirements if this data is submitted for review.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s).: 8501
DP Barcode(s): D168263
Subject: Reregistration of Ethephon. Rhone-Poulenc Letter of 7/29/91.
From: P. Deschamp
To: C. Peterson
Dated: 10/18/91
MRID(s): None

CBRS No(s).: 10460
DP Barcode(s): D181875
Subject: Ethephon Reregistration. Product Chemistry Guideline 63-17 Storage Stability.
From: A. Aikens
To: L. Propst/C. Peterson
Dated: 10/9/92
MRID(s): 42430501

CBRS No(s).: 12006
DP Barcode(s): D192173
Subject: Addendum to the Product Chemistry Chapter for the Ethephon Reregistration Eligibility Decision (RED) Document.
From: B. Cropp-Kohlligian
To: L. Propst/J. Loranger
Dated: 3/29/95
MRID(s): None

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

41154505 Helfant, L.; Castillo, M. (1989) Ethephon Manufacturing Use Product Base 250: Product Identity and Composition: Unpublished compilation prepared by Rhone-Poulenc Ag Co. 96 p.

41154506 Helfant, L. (1989) Ethephon Manufacturing Use Product Base 250: Physical and Chemical Characteristics: Project No. 866/C10. Unpublished Compilation prepared by Rhone-Poulenc Ag Co. 214 p.

41267001 Helfant, L. (1989) Ethephon Manufacturing Use Product: Base 250: Analysis and Certification of Product Ingredients: Laboratory Project No. 866 C10: Study No. AC-89-005. Unpublished study prepared by Rhone-Poulenc AG Co. in cooperation with Lancaster Laboratories, Inc. 321 p.

42430501 Helfant, L. (1992) Ethephon Base 250 Storage Stability Study: Lab Project Number: AC-91-008: 41247. Unpublished study prepared by Rhone Poulenc Ag Co. 50 p.

Case No. 0382
Chemical No. 099801

Case Name: Ethephon
Registrant: Aventis Cropscience USA LP
Product(s): 71.3% FI (EPA Reg. No. 264-511)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ^a	MRID Number ^b
830.1550	Product identity and composition	Y	<u>product jacket</u>
830.1600	Description of materials used to produce the product	Y	<u>41154505</u>
830.1620	Description of production process	Y	41154505
830.1670	Discussion of formation of impurities	Y	41154505
830.1700	Preliminary analysis	Y	41267001
830.1750	Certified limits	Y	<u>product jacket</u>
830.1800	Enforcement analytical method	Y	41267001
830.6302	Color	Y	41267001
830.6303	Physical State	Y	41267001
830.6304	Odor	Y	<u>41267001</u>
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	N	
830.6314	Oxidation/reduction: chemical incompatibility	Y	41267001
830.6315	Flammability	Y	41267001
830.6316	Explosibility	Y	41267001
830.6317	Storage Stability	Y	<u>42430501</u>
830.6319	Miscibility	Y	41267001
830.6320	Corrosion Characteristics	Y	41267001
830.7000	pH	Y	41267001
830.7050	UV/Visible absorption	N	
830.7100	Viscosity	Y	41267001
830.7200	Melting point/melting point range	Y	41267001
830.7220	Boiling point/boiling point range	N/A	
830.7300	Density/relative density/bulk density	Y	41267001
830.7370	Dissociation constants in water	Y	41267001
830.7550/7560/7570	Partition coefficient (n-octanol/water)	Y	41267001
830.7840/7860	Solubility	Y	41267001
830.7950	Vapor Pressure	Y	41267001

^a Y = Yes; N = No; N/A = Not Applicable.

^b Unbolded citations were reviewed in the Ethephon Reregistration Standard Update dated 4/23/91; underlined citations were initially reviewed in the Ethephon Reregistration Standard Update dated 4/23/91 and were re-evaluated based on the conclusion of D168263, dated 10/18/91, by P. Deschamp that the 71.3% FI is the practical equivalent of the TGAI; the **bolded** citation was reviewed under CBRS No. 10460, D181875, dated 10/9/92, by A. Aikens.

RESIDUE CHEMISTRY CONSIDERATIONS

(Shaughnessy No. 099801; Case 0382)

(DP Barcode Nos. D280985, D283022, & D283027)

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A. INTRODUCTION

Ethephon [(2-chloroethyl) phosphonic acid] is a plant growth regulator that promotes fruit ripening, abscission, flower induction, and other responses by releasing ethylene gas, a natural plant hormone.

B. USE PATTERN SUMMARY

1. Product List

A REFs search conducted 5/14/02 indicated that there are ten end-use products (EPs) of ethephon presently registered to Rhone Poulenc Ag Company that may be used on food/feed crops grown in the U.S.; these EPs are soluble concentrate/liquids (SC/Ls) and emulsifiable concentrates (ECs) and are presented below:

Table 1. Ethephon End-Use Products with Food/Feed Uses Registered to Aventis CropScience.

EPA Registration Number	Formulation	Label Date
264-257 ^a	4 lb/gal SC/L	6/98
264-263	0.33 lb/gal SC/L	7/97
264-267 ^b	2 lb/gal SC/L	3/01
264-377	4 lb/gal SC/L	7/97
264-380	4 lb/gal EC	7/97
264-418	6 lb/gal SC/L	7/97
264-543	0.33 lb/gal SC/L	7/97
264-564	4 lb/gal EC	5/97
264-585	6 lb/gal EC	11/99
264-703 ^c	6 lb/gal EC	4/02

^a Formulations include the following SLNs: PR890002, and HI840004.

^b Formulations include the following SLNs: CA760194, NC820007, and VA830017.

^c Formulation also includes cyclanilide at 0.375 lbs ai/gal.

2. Use Pattern

All pertinent product labels must be amended to reflect a maximum allowable use rate of 2 lb ai/A/season for application of ethephon to cotton. Label directions for apples, crabapples, carob, and olives that are for ornamental use only must be clearly designated as such on all pertinent labels.

A comprehensive summary of the registered food/feed use patterns of ethephon, based on these product labels, is presented in Table A. The conclusions regarding the reregistration eligibility of

ethephon on the crops listed in Table B are based on the use patterns described herein which are registered by the basic producer, Rhone-Poulenc. When end-use product data call-ins (DCIs) are developed (e.g. at issuance of the RED), RD should require that all end-use product labels (e.g. MAI labels, special local needs (SLNs), and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels considered herein.

Table 2. Food/Feed Use Patterns Subject to Reregistration for Ethephon (Case 0382).

Site	Application Type Application Timing Application Equipment	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Reentry Interval (Hours)	Use Limitations
Crop Uses							
Apple							
	Foliar Fruit thinning 2 to 4 weeks after full bloom Ground equipment	2 lb/gal SC/L (264-267) (NC820007)	2.0	2.0	7	48	The SLN No. NC820007 permits one broadcast foliar ground application to Spur Red Delicious apple trees in NC at a maximum of 0.5 lb ai/100 gal at up to 400 gal/A (2 lb ai/A) no PHI is listed.
Apple and crabapple (fruit elimination) ^{1,2}							
	Foliar Fruit removal At flower bud to full bloom stage, prior to fruit set Ground equipment	0.33 lb/gal SC/L (264-263) 0.33 lb/gal SC/L (264-543)	0.13 oz ai/gal 0.12 oz ai/gal		NA	24	For elimination of nuisance fruit on ornamentals only.
Barley							
	Foliar, broadcast Early to late boot stage prior to awn emergence Ground and aerial equipment	4 lb/gal SC/L (264-377)	0.5	0.5	40	24	Apply ground and aerial applications in a minimum of 7 and 3 gal/A, respectively. Grazing or foraging by livestock or cutting for hay or silage are prohibited. ³ Mature straw at normal harvest may be consumed by animals. A 30-day plant-back interval is specified.
Blackberry							
	Foliar, broadcast Ground equipment	2 lb/gal SC/L (264-267)	2.0	2.0	3	48	For use on blackberries in OR and WA only.

Site	Application Type Application Timing Application Equipment	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Reentry Interval (Hours)	Use Limitations
Blueberry							
	Foliar, broadcast Ground and aerial equipment	2 lb/gal SC/L (264-267)	2.0	2.0	NS	48	Not for use on blueberries in CA. Apply ground and aerial applications in a minimum of 100-200 gal/A and 10 gal/A, respectively.
Cantaloupe							
	Foliar Aerial or ground equipment	2 lb/gal SC/L (264-267)	0.75	0.75	2	24	Ground and aerial applications can be made in a minimum of 40 and 10 gal/A, respectively. Only ground equipment may be used for application in CA and AZ. Aerial or ground applications are allowed in TX. A 30-day plant-back interval is specified.
Carob (fruit elimination)^{1,2}							
	Foliar At flower bud to full bloom stage, prior to fruit set Ground equipment	0.33 lb/gal SC/L (264-263) 0.33 lb/gal SC/L (264-543)	0.07 oz ai/gal 0.06 oz ai/gal		NA	24	For the elimination of nuisance fruit on ornamentals only.
Cherry (sweet and tart)							
	Foliar Fruit loosening Apply at stage 3 fruit development Ground equipment	2 lb/gal SC/L (264-267)	1 (sweet) 0.25 (tart)	1	7	24	This use is not permitted in CA. Apply in a minimum of 50 gal/A.
Coffee							

Site	Application Type Application Timing Application Equipment	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Reentry Interval (Hours)	Use Limitations
	Foliar Coffee cherry ripener Harvest aid	4 lb/gal SC/L (264-257)	0.42	0.84	5		Apply up to 200 gal/A (max. 0.42 lb ai/A).
Cotton							
	Foliar, Broadcast Boll opening Preconditioning for defoliation Defoliation Ground and aerial equipment	6 lb/gal EC (264-418) (264-703)	2 1 0.25	2	7	48	Apply in a minimum of 2 gal/A by air and 15 gal/A by ground. In AZ and CA, aerial spray volume must be at least 5 gal/A. A 30-day plant-back interval is specified. EPA Reg. No. 264-703 specifies 3 gal/A by air and 10 gal/A by ground. A 30 day plant-back interval is specified for small grains and leafy vegetables and a 4 month plant-back interval for all other crops.
	Foliar Boll opening Preconditioning for defoliation Aerial or ground equipment	4 lb/gal EC (264-380)	2 1		7	24	Apply in a minimum of 2 gal/A by air and 15 gal/A by ground. In AZ and CA, aerial spray volume must be at least 5 gal/A. Do not mix with defoliant or desiccants in CA and AZ. A 30-day plant-back interval is specified.
Cucumber (hybrid seed production)^{1,4}							
	Foliar Apply at 2-leaf stage Ground equipment	0.33 lb/gal SC/L (264-263)	0.08	0.16	NA	24	For hybrid seed production. Do not use on cucumbers to be harvested for fresh or processed markets. Do not harvest any treated cucumbers or squash for human or animal consumption. Treatments are to be made for seed production only. Spray plants at the two leaf stage.

Site	Application Type Application Timing Application Equipment	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Reentry Interval (Hours)	Use Limitations
			0.25 (CA only)	1.5 (CA only)	60		In CA only, six applications are allowed beginning at the first true leaf stage and at 3- to 10-day intervals thereafter.
Grape							
	Foliar Prior to harvest Ground equipment	2 lb/gal SC/L (264-267)	0.5 lb ai/A (AZ and CA only)	0.5 lb ai/A	14	48	For use on table grapes in AZ and CA only. Also for use on Thompson seedless for raisin production.
Macadamia Nut							
	Foliar Prior to harvest Ground equipment	4 lb/gal SC/L (HI840004)	0.7 lb ai/100 gal	1	5	24	SLN No. HI840004 permits one application to leaves and nuts in HI only at 100-200 gal/A. Grazing and foraging of cover crops is not permitted.
Olive (fruit elimination) ^{1,2}							
	Foliar At flower bud to full bloom stage, prior to fruit set Ground equipment	0.33 lb/gal SC/L (264-263) 0.33 lb/gal SC/L (264-543)	0.13 oz ai/gal 0.12 oz ai/gal		NA	24	For the elimination of nuisance fruit, not intended for use as a thinning agent in commercial fruit production.

Site	Application Type Application Timing Application Equipment	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Reentry Interval (Hours)	Use Limitations
Pepper							
	Foliar Apply at fruit maturity Ground and aerial equipment	2 lb/gal SC/L (264-267) (CA760194)	1	1	5	24	SLN No. CA760194 permit a single aerial or ground application to chili, bell, and pimento peppers only in CA. Apply aerial and ground applications in a minimum of 15 and 40 gal/A, respectively. Crop is to be harvested at optimum maturity generally 14 or more days following treatment. A 30-day plant-back interval is specified.
Pineapple							
	Foliar broadcast Floral induction Fruit maturation Ground equipment	4 lb/gal SC/L (264-257)	2	3	2	48	Apply in a minimum of 100 gal/A. Grazing of pineapple forage is not permitted.
Pumpkin (hybrid seed production) ¹							
	Foliar Ground equipment	0.33 lb/gal SC/L (264-263)	0.25	1.5	42	24	For hybrid seed production in IL only. Six applications permitted at 7- to 10-day intervals beginning at the 2-4 leaf stage. Apply in a minimum of 40 gal/A.
					60		For hybrid seed production in CA only. Six applications permitted at 3- to 10-day intervals beginning at the first true leaf stage. Apply in a minimum of 40 gal/A.

Site	Application Type Application Timing Application Equipment	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Reentry Interval (Hours)	Use Limitations
Squash (hybrid seed production) ¹							
	Foliar Apply at 2- to 4-leaf stage Ground equipment	0.33 lb/gal SC/L (264-263)	0.08	0.16	NA	24	For hybrid seed production. Do not harvest any treated cucumbers or squash for human or animal consumption. Treatments are to be made for seed production only. Spray plants at the two leaf stage.
			0.25	1.5	60		In CA only. Six applications permitted at 3- to 10-day intervals beginning at the first true leaf stage. Apply in a minimum of 40 gal/A. Do not use on squash to be harvested for fresh or processed markets.
Sugarcane							
	Foliar, broadcast Prior to floral initiation Aerial equipment	4 lb/gal SC/L (264-257)	0.5	0.5	2 months	48	Application permitted in HI only. Grazing of sugarcane forage is not permitted.
Tobacco (Flue-cured only) ¹							
	Foliar, directed Foliar, broadcast At leaf maturity Ground equipment	2 lb/gal SC/L (264-267) (264-292)	1 2	2.0	2	24	A 30-day plant-back interval is specified and the 264-292 label prohibits the use of surfactants or wetting agents.
	Foliar, directed Foliar, broadcast At leaf maturity Ground equipment	6 lb/gal EC (264-418)	1 2		24	48	A 30-day plant-back interval is specified.

Site	Application Type Application Timing Application Equipment	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Reentry Interval (Hours)	Use Limitations
Tomato (fresh market)							
	Foliar, broadcast At fruit maturity Aerial and ground equipment	2 lb/gal SC/L (264-267)	1.25	1.25	3	24	This use is permitted only in CA. Do not use on greenhouse grown tomatoes. Apply in a minimum of 40 (ground) and 10 (air) gal/A. A 30-day plant-back interval is specified.
	Foliar At fruit maturity Ground equipment	0.33 lb/gal SC/L (264-263)	0.3 oz ai/gal	0.3 oz ai/gal		24	For Home garden tomato production: the PHI for fresh market tomatoes in CA is 3 days.
Tomato (for processing)							
	Foliar, broadcast At fruit maturity Aerial and ground equipment	2 lb/gal SC/L (264-267)	1.63	1.63	3	24	Apply in a minimum of 20 (ground) and 10 (air) gal/A. A 30-day plant-back interval is specified. Do not use on greenhouse grown tomatoes.
	Foliar At fruit maturity Ground equipment	0.33 lb/gal SC/L (264-263)	0.3 oz ai/gal	0.3 oz ai/gal		24	For Home garden tomato production: the PHI for tomatoes for processing is 14 days.
Walnut							
	Foliar Ground Equipment	2 lb/gal SC/L (264-267)	1.25	1.25	5	24	Apply in a minimum of 100 gal/A
Wheat							

Site	Application Type Application Timing Application Equipment	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Reentry Interval (Hours)	Use Limitations
	Foliar, broadcast Early to late boot stage prior to awn emergence Ground and aerial equipment	4 lb/gal SC/L (264-377)	0.5	0.5	40	24	Apply ground and aerial applications in a minimum of 7 and 3 gal/A, respectively. Grazing or foraging by livestock or cutting for hay or silage are prohibited. ⁴ Mature straw at normal harvest may be consumed by animals. A 30-day plant-back interval is specified.

¹ Non-food use.

² Label directions for apples, crabapples, carob, and olives that are for ornamental use only must be clearly designated as such on all pertinent labels.

³ These label restrictions are no longer appropriate since the Agency has determined that barley and wheat forage and hay are not under grower/farmer control (OPPTS 860 Guidelines), therefore, are not practical or enforceable.

⁴ The registrant has deleted the use of ethephon on cucumbers for fresh or processed markets from the 0.33 lb/gal SC/L product label (EPA Reg. No. 264-263 dated 8/11/94). The Agency, has hereby, rescinded the previous label amendment requirement to limit use to states representing cucumber seed production regions but has imposed a new label amendment requirement to prohibit the harvesting of any treated pumpkins for human or animal consumption and specify that treatments are to be made to pumpkins for seed production only.

C. SUMMARY OF RESIDUE CHEMISTRY DATA REQUIREMENTS

Table 3. Summary of Residue Chemistry Data Requirements for Ethephon (PC Code 099801).

OPPTS Guideline No.	Guideline Description / Commodity	§180.300 Tolerances (ppm)	Must Additional Data Be Submitted?	MRID Nos. ¹	Comments
860.1200	Directions for Use	Not applicable (NA)	Yes ²		
860.1300	Nature of the Residue - Plants	NA	No	00038793 00038796 00053153 00054018 00054021 00067489 00081783 00088983 00097422 00108993 00116123 00117893 00121613 00122410	
860.1300	Nature of the Residue - Livestock	NA	No	00118508 00141506 00165339 42236701 ⁴ 43514701, 43879401 ³	
860.1340	Residue Analytical Method				

	- Plant Commodities	NA	No	00030190 00036500 00038795 00038797 00038880 00038881 00042977 00041465 00047911 00047913 00053149 00103287 00108992 00116123 00117893 00121613 00122410 00122421 00122433 00122435 00123237 00128726 00145613 Makhijani (1971), Zee (1984), 41296201 ⁶ 41668205 41668207 41704501 42268901 through -03 ⁷ 42298201 ⁷ 42300801 through -07 ⁷ 42410401 through -03 ⁸ 42718101 ⁹ 42957302 ¹⁰	
	- Livestock Commodities	NA	No	00100517 00121613 00122421 00142265 Wright and Rains (1984), 41296201 ⁶ 42957301 ¹⁰ 44036001 ⁵	
860.1360	Multi-Residue Method	NA	No	41296201 ⁶	
860.1380	Storage Stability Data				

	- Plant Commodities		No ¹¹	00151127 41668201 41668202 41668203 41668204 41668206 41668208 41668209 41668210 41668211 41668212 41668213 41668215 42010401 ¹² 42410401 through 03 ⁸ 42464401 ¹³ 42268904 through 09 ⁷ 42300801 through 08 ⁷ 42718101 ⁹ 42957301 ¹⁰	
	- Livestock Commodities		No ¹¹		
860.1400	Magnitude of the Residue - Water, Fish, and Irrigated Crops	NA	NA		
860.1460	Magnitude of the Residue - Food Handling	NA	NA		
860.1480	Magnitude of the Residue - Meat, Milk, Poultry, Eggs (MMPE) ³⁷				
	- Fat, meat, and meat byproducts of cattle, goat, hog, horse, and sheep	0.1 (fat, meat, and mbyp)	No	00083773 00100517 00121613 44100201 ⁴¹	Adequate feeding study data are available.
	- Milk	0.1	No	44100201 ⁴¹	Adequate feeding study data are available.
	- Eggs, fat, meat, and meat byproducts of poultry	None	No	44100202 ⁴¹	Adequate feeding study data are available.
860.1500	Crop Field Trials				
	<u>Fruiting Vegetable Group</u> - Pepper	30	No	00061719 00121613 43644303 ¹⁴	Adequate residue data are available.
	- Tomato	2.0	No	00121613 42016701 ¹⁵ 42268903 ⁷ 43532401 ⁴⁰	Adequate residue data are available.

	<u>Cucurbit Vegetables Group</u> - Cantaloupe	2.0	No	00117893 41668207 42718101 ⁹ 43660201 ¹⁶	Adequate residue data are available.
	- Cucumber	0.1	No ¹⁷	PP#9E2225 (098344)	Non-food use.
	- Pumpkin	0.1	No ¹⁸	00122717	Non-food use.
	<u>Pome Fruit Group</u> - Apple	5.0	No	00061717 00108992 00123222 41872502 ²⁰ 42379101 ²¹	Adequate residue data are available.
	<u>Stone Fruit Group</u> - Cherry	10	No	00081782 00136287	Adequate residue data are available.
	<u>Small Fruits and Berries Group</u> - Blackberry	30	No	00121613 41668205	Adequate residue data are available.
	- Blueberry	20	No	00121613	Adequate residue data are available.
	- Cranberry	5.0	No ¹⁹	00121613	Not being supported by registrant.
	<u>Tree Nuts Group</u> - Macadamia	0.5	No	00128726	Adequate residue data are available.
	- Walnut	0.5	No	00038795 00117752 42464401 ¹³	Adequate residue data are available.
	<u>Cereal Grains Group</u> - Barley	2.0	No	00103287	Adequate residue data are available.
	- Wheat	2.0	No	00103287 42268902 ⁷	Adequate residue data are available.
	<u>Forage, Fodder, and Straw of Cereal Grains</u> - Barley straw	10	No ²⁵	00103287	Adequate residue data are available.
	- Barley forage	None	No ²⁵	00103287	

- Barley hay	None	No ²⁵	00103287	
- Wheat straw	10	No ²⁵	00103287 42268902 ⁷	Adequate residue data are available.
- Wheat forage	None	No ²⁵		
- Wheat hay	None	No ²⁵		
- Wheat aspirated grain fractions	None	No ²⁵	42268901 ⁷	Adequate residue data are available.
<u>Miscellaneous Commodities</u> - Coffee Bean	0.1	No	00041465 45195801 ⁴³	Adequate residue data are available.
- Cotton, seed	2.0	No ²⁶	00030190 00122423 41704501 43368458 ⁴⁴ 43868343 ⁴⁵	Adequate residue data are available.
- Cotton gin byproducts	None	No	43368458 ⁴⁴ 43868343 ⁴⁵	Adequate residue data are available.
- Fig	5.0	No ¹⁹	00036500	
- Grape	2.0	No	00053150 00051353 00080482 00121613 41872501 ²⁰ 42116501 ²³ 42410301 ²⁴	Adequate residue data are available.
- Pineapple	2.0	No	00040268 00040269 00054022 00116123 00122452 00123222 42298201 ⁷	Adequate residue data are available.
- Sugarcane	0.1	No	00032573 00145613 40954401 ²⁷	Adequate residue data are available.
- Tobacco	N/A ²⁸	No	00122410 41746501 ²⁹	Adequate residue data are available.

860.1520	<u>Magnitude of the Residue in Processed Food</u> ³⁰				
	-Apple, juice	None ³¹	No	41872502 ²⁰ 42379101 ²¹	Adequate residue data are available.
	-Barley, bran	5.0 ³²	No	00103287 42268901 ⁷	Adequate residue data are available.
	-Barley, pearled barley	5.0	No	00103287 42268901 ⁷	Adequate residue data are available.
	-Coffee, instant	None	No	45195801 ⁴³	Adequate residue data for coffee, freeze-dried were submitted.
	-Coffee, roasted bean	None	No	45195801 ⁴³	Adequate residue data are available.
	-Grape, raisins	12	No ³³	00080482 00121613	Adequate residue data are available.
	-Grape, juice	None	No ³³	00053150	Adequate residue data are available.
	-Pineapple, juice	None	No	42298201 ⁷	Adequate residue data are available.
	-Sugarcane, molasses	1.5	No	40954401 ²⁷ 42381701 ³⁴	Adequate residue data are available.
	-Tomato, paste	None	No	42016701 ¹⁵	Adequate residue data are available.
	-Wheat, milling fractions, except flour	5.0	No	42268901 ⁷	Adequate residue data are available.
	-Wheat, bran	5.0 ³²	No	00103287 42268901 ⁷	Adequate residue data are available.
	<u>Magnitude of the Residue in Processed Feed</u> ³⁰				

	-Cottonseed, meal	None	No	00030190 00122423 ³⁵ PP#4G04414 ³⁵	Adequate residue data are available.
	-Pineapple, bran	None ³⁶	No	42298201 ⁷	No longer a feed item.
	-Grape, raisin waste	65	No	00080482 41872501 ²² 42116501 ²³ 42410301 ²⁴	No longer a feed item.
	-Sugarcane, molasses	1.5	No	40954401 ²⁷ 42381701 ³⁴	Adequate residue data are available.
	-Wheat, milling fractions, except flour	5.0	No	42268901 ⁷	Adequate residue data are available.
860.1650	Submittal of Analytical Reference Submittal	None	Yes	None	Analytical reference standards must be submitted upon request by the Agency.
860.1850	Confined Rotational Crops	None	No	43143601 ³⁸ 43725101 ⁴²	Adequate residue data are available.
860.1900	Field Rotational Crops	None	No	43143601 ³⁹	

1. **Bolded** references were reviewed in the Reregistration Standard Update dated 4/23/91. Unbolded references were reviewed in the Registration Standard dated 4/19/88. Otherwise, reviewed as noted.

2. As required by the 1991 Registration Standard, all pertinent product labels must be amended to reflect a maximum allowable use rate of 2 lb ai/A/season for application of ethephon to cotton. In addition, label directions for apples, crabapples, carob, and olives that are for ornamental use only should be clearly designated as such on all pertinent labels. The Agency has hereby rescinded the previous label amendment requirement to limit the use of the 0.33 lb/gal SC/L end-use product (EPA Reg. No. 264-263) to states representing cucumber seed production regions and has imposed a requirement to further amend the currently registered 0.33 lb/gal SC/L product label (EPA Reg. No. 264-263 dated 8/11/94) to prohibit the harvesting of any treated pumpkins for human or animal consumption and specify that treatments are to be made to pumpkins for seed production only.

3. DP Barcode D211170, 2/21/02, T. Morton.

4. CBRS No. 9610, DP Barcode D176113, 9/16/92, B. Cropp-Kohliligian.

5. DP Barcode D227485, 2/21/02, T. Morton.

6. CBRS No. 7167, 11/2/90, W. Smith.
7. CBRS No. 9887, DP Barcode D178357, 10/27/92, B. Cropp-Kohlligian.
8. CBRS No. 10341, DP Barcode D181311, 3/30/93, P. Deschamp.
9. CBRS No. 11681, DP Barcode D190075, 5/10/93, P. Deschamp.
10. CBRS Nos. 12698 and 12727, DP Barcodes D195976 and D196179, 6/27/94, B. Cropp-Kohlligian.
11. Storage stability data on processed samples of cottonseed oil and apple juice were required to support available magnitude of the residue data for processed raw agricultural commodities (Greybeard Committee review dated 10/14/93, and CBRS Nos. 12034 and 12084, DP Barcodes D192265 and D192479, 2/10/94, P. Deschamp). These data have been submitted and deemed adequate (DP Barcode D280668, 2/26/02, T. Morton).
12. CBRS No. 8267, DP Barcode D168968, 4/4/92, P. Deschamp.
13. CBRS No. 10585, DP Barcode D182586, 2/16/93, A. Aikens.
14. DP Barcode D280668, 2/26/02, T. Morton.
15. Tomato paste is currently considered a processed food. Data were submitted (MRID 42016701) and reviewed by CBRS (DP Barcode D169084; CBRS No. 8635; memo by P. Deschamp dated 3/31/92) which indicate that residues of ethephon do not concentrate in tomato paste and, therefore, no tolerance is needed. No additional tomato paste data are required.
16. DP Barcode D280665, 2/26/02, T. Morton.
17. The registrant has amended the 0.33 lb/gal SC/L label (EPA Reg. No. 264-263 dated 8/11/94) deleting the use on cucumbers grown for fresh market or processing and maintaining only the seed production. The Agency has hereby rescinded the previous requirement to further amend the 0.33 lb/gal SC/L label (EPA Reg. No. 264-263) limiting use to states representing cucumber seed production regions. In the case of ethephon for use on cucumbers grown for seed as directed on the 0.33 lb/gal SC/L product label (EPA Reg. No. 264-263 dated 8/11/94), the Agency has hereby concluded that this use qualifies as a non-food use and, therefore, no additional residue data for cucumbers will be required. The 0.1 ppm tolerance for cucumbers should be revoked.
18. The Agency has hereby extended the non-food use determination for ethephon used on cucumbers grown for seed as directed on the 0.33 lb/gal SC/L product label (EPA Reg. No. 264-263 dated 8/11/94) to include pumpkins and squash grown for seed, pending a further amendment to the label to prohibit the harvesting of any treated pumpkins for human or animal consumption and specify that treatments are to be made to pumpkins for seed production only. No additional residue data for pumpkins will be required and the 0.1 ppm tolerance for pumpkins should be revoked.
19. Cranberries and figs have been deleted from ethephon product labels. Tolerances for residues in/on these commodities should be revoked. However, if the registrant or another party are interested in supporting the established tolerances on any of these commodities, appropriate residue data must be submitted.
20. CBRS No. 8564, DP Barcode D168467, 4/1/92, P. Deschamp.
21. CBRS No. 10246, DP Barcode D180648, 9/8/92, D. McNeilly; and CBRS No. None, 2/22/93, B. Cropp-Kohlligian.
22. CBRS No. 7936, DP Barcode D164042, 9/26/91, B. Cropp-Kohlligian; and CBRS No. 8136, DP Barcode

D165460, 9/27/91, B. Cropp-Kohlligian.

23. CBRS No. 9113, DP Barcode D172474, 2/12/92, B. Cropp-Kohlligian.

24. CBRS No. 11467, DP Barcode D188672, 9/22/93, B. Cropp-Kohlligian; and CBTS No. 10510, DP Barcode D182143, 12/20/93, G. Kramer.

25. The Agency currently recognizes wheat grain, forage, hay, straw, and aspirated grain fractions as the raw agricultural commodities of wheat and barley grain, forage, hay, and straw as the raw agricultural commodities of barley. Wheat grain dust data (MRID 42268901) were previously submitted which indicated that residues of ethephon do not concentrate in aspirated wheat grain fractions. In accordance with guidance (issued June 2, 1994) on aspirated grain fractions (grain dust), additional wheat aspirated wheat grain fraction data are not required and no tolerance is needed for residues of ethephon in/on aspirated wheat grain fractions. Existing wheat grain data have been translated to barley grain. A waiver was granted from the requirement for residue data on wheat hay and forage by the HED Greybeard Committee (3/1/96).

26. Assuming that all pertinent product labels are amended to reflect a maximum allowable use rate of 2 lb/A/season for application of ethephon to cotton and the registrant proposes increasing the established tolerance for residues of ethephon in/on cottonseed from 2 ppm to 6 ppm (CBRS No. 17353 & 17354, D227554, 10/29/96, G. Kramer), no additional data are required.

27. CBRS Nos. 6472, 6473, and 6474, 8/7/90, S. Funk.

28. Use of a pesticide on tobacco does not require a tolerance or an exemption from the requirement to obtain a tolerance.

29. CBRS No. 12013, DP Barcode D192207, 2/8/94, P. Deschamp; and CBRS No. 7678, DP Barcode D161111, 1/9/92, F. Toghrol.

30. Available processing data indicate that residues of ethephon do not concentrate in the following processed commodities: wet apple pomace, pearled barley; tomato puree, tomato paste, tomato juice, wheat flour, cottonseed hulls, cottonseed crude and refined oil, and pineapple juice.

31. Apple processing data indicate that residues of ethephon concentrate in apple juice. A tolerance of 10 ppm for residues of ethephon in apple juice must be established.

32. Translated wheat bran and flour processing data to barley bran and flour.

33. After an appropriate tolerance is determined for residues of ethephon in/on grapes, a tolerance for raisins must be proposed using a concentration factor of 4.7x for raisins (CBTS No. 10510, DP Barcode D182143, 12/20/93, G. Kramer). The theoretical maximum concentration factor for grape juice is 1.2X. Therefore, no tolerance is required for ethephon residues in grape juice.

34. D280664, 6/18/02, T. Morton.

35. Two cottonseed processing studies (MRIDs 00030190 and 00122423) were previously submitted and reviewed in the Ethephon Registration Standard (4/19/88) which concluded that residues of ethephon concentrate in meal (6x), refined oil (2x), and soapstock (4x) but not in hulls or crude oil. CBTS (DP Barcode D159333; CBTS No. 7476; by R. Lascola dated 11/25/91) and CBRS (DP Barcode D187910; CBRS No. 11344; by P. Deschamp dated 4/15/93) have reconsidered available cottonseed processing data and conclude that upon processing, ethephon residues do not concentrate in oil but do concentrate in meal (1.25x). Another cotton processing study was submitted with PP# 4G04414 for tolerances for residues of cyclanilide on cotton using a product with ethephon as a co-active ingredient.

Ethephon residues did not concentrate in any cotton fraction and the concentration factor observed for meal was 0.02X (Memo, G. Kramer 1/30/95; PP#4G04414). Averaging the results of the nine acceptable processing studies yields a concentration factor of 0.7X for cottonseed meal. As ethephon residues do not appear to concentrate in cotton processed commodities, tolerances for these commodities are not required.

36. Currently the only regulated pineapple processed commodities are juice and process residue. Since pineapple bran is no longer considered a feed item, the Agency has hereby determined that a tolerance for residues of ethephon in pineapple bran is not required. Available pineapple processing data indicate that there is no significant concentration of ethephon residues in pineapple juice and pineapple process residue, no food/feed additive tolerances are needed for these commodities.

37. New ruminant and poultry feeding studies were reviewed and found to be adequate (CBRS No. 17353 & 17354, D227554, 10/29/96, G. Kramer, PP#6F4743).

38. DP Barcode D200239, 3/29/95, B. Cropp-Kohlligian.

39. Limited field rotational crop studies are not required and no tolerances are needed for ethephon residues in rotational crop.

40. D280667, 2/26/02, T. Morton.

41. CBRS No. 17353 & 17354, D227554, 10/29/96, G. Kramer, PP#6F4743.

42. D280663, 5/9/02, T. Morton.

43. D283033, 6/20/02, T. Morton.

44. D207953, G. Kramer, 1/30/95; PP#4G04414.

45. D224555, G. Kramer, 5/15/96.

D. RESIDUE CHARACTERIZATION

General Discussion on Residue Chemistry of Ethephon

1. Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on tomato, cantaloupe, apple, fig, pineapple, tobacco, grape, walnut, filbert, cherry, tangerine, and lemon

metabolism data. Ethephon degrades to ethylene, phosphate, and chloride. Data indicate that translocation of ethephon to fruits may occur following application to leaves. The residue of concern in plants is ethephon *per se* (T. Morton, D282695, 5/28/02).

2. Nature of the Residue in Livestock

Ruminant

The qualitative nature of the residue in ruminants is adequately understood based on goat metabolism data. In ruminant tissues and milk, ethephon is incorporated into natural products (glutathione conjugates, protein, glycogen, triglycerides) and expired as $^{14}\text{CO}_2$ and ^{14}C -ethylene. No residues of ethephon were detected in the goat metabolism study; however, residues of ethephon were detected in ruminant tissues and milk in a ruminant feeding study which was conducted at exaggerated rates. The residue of concern in milk and ruminant tissues is ethephon *per se* (T. Morton, D282695, 5/28/02).

Poultry

The qualitative nature of the residue in poultry is adequately understood based on poultry metabolism data. The metabolic pathway for ethephon in poultry as proposed by the registrant proceeds via initial cleavage of chlorine and formation of 2-hydroxy ethyl phosphonic acid (HEPA) followed by formation of intermediates that are incorporated into the amino acid and fatty acid biosynthetic pathways. The residue of concern in eggs and poultry tissues is ethephon *per se* (T. Morton, D282695, 5/28/02).

3. Residue Analytical Methods

Adequate methods for purposes of enforcement of ethephon tolerances in plant commodities, ruminant tissues and milk are available. The Amchem-Plant Method (PAM, VOL. II, Method I) is the recommended method for enforcement purposes for plant commodities and processed products other than wheat and barley straw. The Amchem-Cereal Method (forwarded to FDA for inclusion in the PAM, VOL. II, Method II) is the recommended method for enforcement purposes for wheat and barley straw. The Union Carbide-Animal Method (forwarded to FDA for inclusion in the PAM, VOL. II, Method III) is the recommended method for enforcement purposes for milk and animal tissues.

The plant and animal analytical methods currently recommended for enforcement purposes employ the use of diazomethane as a methylating agent and HED (in the 1991 Registration Update) required the registrant to revise the currently accepted enforcement methods to replace diazomethane with a safer methylating agent or provide documentation supporting the need for diazomethane if a suitable alternative methylating agent is impractical. Rather than address Agency concerns about the use of diazomethane as a methylating agent, Rhone-Poulenc submitted new plant and animal methods for enforcement purposes which principally involve the

decomposition of ethephon to ethylene to determine the residues of ethephon in/on apples, barley grain, barley straw, blackberries, cantaloupes, cherries, cottonseed, cucumbers, grapes, Macadamia nuts, peppers, pineapples, tobacco, tomatoes, sugarcane, walnuts, wheat grain, wheat straw, meat, milk and eggs. The Agency reviewed the new proposed plant and animal enforcement methods and concluded that in order for the proposed methods to be considered adequate for enforcement purposes, they must undergo a successful independent laboratory validation (ILV) as described in PR Notice 88-5 (7/15/88) followed by a successful method validation by the Agency. The ILV has been reviewed and found adequate by HED (T. Morton, 5/2/02, D280666). The method will be forwarded to the Agency laboratory for method validation.

The registrant successfully radiovalidated the new livestock residue analytical method using samples from the new poultry metabolism study (T. Morton, D227485, 2/21/02).

4. Multiresidue Method (MRM) Testing

The FDA Pestdata (PAM Vol. I Appendix, 8/93) indicates that ethephon is not recovered through any of the Multiresidue Protocols.

5. Storage Stability Data

Adequate storage stability data are available for apples, barley grain and straw, blackberries, cherries, cottonseed, grapes, Macadamia nuts, peppers, pineapples, tobacco, tomatoes, walnuts, and wheat grain and straw. Storage stability data indicate that residues of ethephon are generally stable for intervals of up to 24 months in frozen commodities. Ethephon residues are also stable in freeze-dried cherries, pineapple, apples, grapes, tomatoes, and blackberries for up to 24 months stored at room temperature.

The registrant has submitted storage stability data on processed samples of cottonseed oil and apple juice to support available magnitude of the residue data for processed raw agricultural commodities (Greybeard Committee review dated 10/14/93). Ethephon residues are stable in apple juice and cottonseed oil for at least 12 months when stored frozen at -20 C.

Available storage stability data from the original livestock feeding studies adequately demonstrate that residues of ethephon are stable in meat, milk, and eggs for up to 12 months, 4 months, and 15 months, respectively, when samples are stored in polypropylene bottles at approximately -20°C. Samples from the most recent livestock feeding studies were analyzed within 1 month, therefore, no storage stability data are necessary for these samples.

All future plant and animal magnitude of the residue studies must have supporting storage stability data. The Agency prefers that concurrent storage stability studies be conducted.

6. Magnitude of the Residue in Crop Plants

The following is a summary of the magnitude of the residue studies for registered food/feed crops.

Apple: Adequate field trial data for apples have been submitted and evaluated. In previous submissions (MRIDs 00061717, 00108992, and 00123222), ethephon residues were 0.3-3.41 ppm in samples harvested 7 days after treatment with a single foliar application of 1.25 lb ai/A (0.6X), 0.22-1.45 ppm in samples harvested 3-6 days after treatment with 1.25 lb ai/A, 0.02-1.78 ppm in samples harvested 9-13 days after treatment with 1.25 lb ai/A, and two samples collected 9 days after application contained residues of 3.96 and 4.88 ppm after treatment with 1.25 lb ai/A. Ethephon residues were 2.33, 4.62, and 7.19 ppm in/on three samples harvested 7 days after treatment with 2.5 lb ai/A (1.25X), 0.52-1.34 ppm in/on three samples harvested 3-6 days after treatment with 2.5 lb ai/A, and 0.51-2.14 ppm in/on two samples collected 10-11 days after treatment with 2.5 lb ai/A.

Data were also submitted for ethephon residues in/on apples after treatment with two foliar applications (MRID 00061717). Ethephon residues were 1.93-2.54 ppm in/on three samples harvested 7 days after treatment with two applications of 1.25 lb ai/A, ethephon residues were 1.57-2.68 ppm in/on six samples harvested 7 days after treatment with two applications of 0.625 lb ai/A. Thirty additional samples collected 9-14 days after treatment with two applications of 0.625-1.1 lb ai/A contained ethephon residues of 0.1-3.16 ppm.

Barley: Adequate field trial data for barley grain and straw have been submitted and evaluated. In a previous submission (MRID 00103287), ethephon residues were <0.02-0.66 ppm in/on barley grain samples harvested 41-68 days after treatment with a single foliar application of 0.5 lb ai/A (1X); one additional sample harvested 68 days after treatment contained 1.73 ppm ethephon residues. Ethephon residues were <0.02-0.06 ppm in barley grain harvested 56-57 days after treatment with 0.75 lb ai/A (1.5X). Ethephon residues were 0.05-1.97 ppm in/on barley straw harvested 41-50 days after treatment with 0.5 lb ai/A.

A waiver was granted from the requirement for magnitude of the residue data for wheat hay and forage by the HED Greybeard Committee because ethephon is applied after the forage/hay stage (3/1/96). Therefore, residue data for barley hay are not required.

Blackberry: Adequate field trial data for blackberries have been submitted and evaluated. In a previous submission (MRID 00121613), ethephon residues were 11.4-22.2 ppm in/on blackberry samples harvested 3 days after treatment with a single foliar application of 2.5 lb ai/A (1.3X) and 0.33-13.7 ppm in/on samples harvested 0-4 days after treatment with 1-1.25 lb ai/A (0.5-0.6X). In another submission (MRID 41668205), ethephon residues in blackberry samples were 12-22, 6.6-11, and 3.0-8.4 ppm 3, 7, and 14 days after treatment with 2.5 lb ai/A, respectively.

Blueberry: Adequate field trial data for blueberries have been submitted and evaluated. In a previous submission (MRID 00121613), ethephon residues were 4.15-16.8 ppm in/on blueberry samples harvested 0 days after treatment with a single foliar application of 2 lb ai/A (1X), 3.17-18.6 ppm in/on blueberry samples harvested 2-7 days after treatment, and 2.01-10.7 ppm in/on blueberry samples harvested 8-14 days after treatment. Ethephon residues were 0.93-5.81 ppm in/on blueberry samples harvested 0-13 days after treatment with 1 lb ai/A. In one field trial in Maine, residues were 6.8-10.9 ppm in/on blueberry samples harvested 39 days after aerial treatment with 2 lb ai/A. Ethephon residues were 3.51-12.9 ppm in/on blueberry samples harvested 7-14 days after treatment with 2 lb ai/A and 4.42-7.34 ppm in/on blueberry samples harvested 7-55 days after treatment with 1-1.75 lb ai/A (0.5-0.9X).

Cantaloupe: Adequate field trial data for cantaloupes have been submitted and evaluated. In a recent submission (MRID 43660201), residues of ethephon in/on cantaloupe samples harvested 2 days after a single treatment by of ethephon at 0.75 lb ai/A (1X) ranged from 0.13 to 0.72 ppm. (HAFT=0.63 ppm).

In a previous submission (MRID 41668207), ethephon residues were 0.03-0.16 ppm in samples harvested 2 days after an aerial treatment with 0.87 lb ai/A (1.2X), 0.03-0.11 ppm in samples harvested 4 days after treatment, and <0.02-0.06 ppm in samples harvested 6 days after treatment. Ethephon residues in/on cantaloupe after ground application of 0.87 lb ai/A were 0.36-0.48, 0.37-0.49, and 0.06-0.07 ppm 2, 4, and 6 days after treatment, respectively.

In another submission (MRID 00117893), ethephon residues were 0.14-0.41 ppm in samples harvested 3 days after treatment with 0.8-0.86 lb ai/A (1.1X), 0.07-0.08 ppm in samples harvested 5 and 6 days after treatment with 0.8-0.86 lb ai/A, 1.05-1.56 ppm in samples harvested 1 and 3 days after treatment with 1.6 lb ai/A, and 0.1-0.3 ppm in samples harvested 3-10 days after treatment with 1.6 lb ai/A.

Cherry: Adequate field trial data for cherries have been submitted and evaluated. In previous submissions (MRIDs 00136287 and 00081782), ethephon residues were <0.01-3.18 ppm in/on tart cherry samples harvested 1-13 days after treatment with a single foliar application of 0.5-0.6 lb ai/A (2-2.4X) which included four samples harvested 7 days after application which contained ethephon residues of <0.01-1.47 ppm, 0.74-10.8 ppm in/on samples harvested 6-14 days after treatment with 1.25-2.5 lb ai/A. Ethephon residues were <0.01-6.92 ppm in/on sweet cherry samples harvested 6-14 days after treatment with a single foliar application of 1.25 lb ai/A (1.3X).

Coffee: Adequate field trial data for coffee have been submitted and evaluated. In a current submission (MRID 45195801), ethephon residues were <0.1-0.49 ppm in/on coffee green bean harvested 4-6 days after the last of two treatments of 0.42 lb ai/A (1X).

Cottonseed: Adequate field trial data for cottonseed have been submitted and evaluated. In a previous submission (MRID 00030190), ethephon residues were <0.01-0.29 ppm in/on

cottonseed samples harvested 6-8 days after treatment with 2 lb ai/A (1X). Ethephon residues were <0.01-0.38 ppm in/on cottonseed samples harvested 10-14 days after treatment, 1.19 ppm in one sample harvested 13 days after treatment, and <0.01-0.16 ppm in/on cottonseed samples harvested 20-21 days after treatment with 2 lb ai/A.

In another submission (MRID 41704501), ethephon residues in/on cottonseed were <0.02-1.8, <0.02-1.8, and <0.02-3.0 ppm in samples harvested 6-7, 9-11, and 13-14 days, respectively, after treatment with 2 applications totaling 2 lb ai/A. Ethephon residues in/on cottonseed were <0.02-2.4 ppm (MRIDs 00122423 and 41704501) in samples harvested 6-14 days after treatment with 1 application of 2 lb ai/A.

In two other submissions (MRIDs 43368458 and 43868343), ethephon residues in/on cottonseed were 0.09-4.93 ppm in samples harvested 7 days after treatment with 1 application of 2 lb ai/A. In addition, cotton gin trash samples were analyzed for ethephon residues and ranged from 6.66-150 ppm.

Grape: Adequate field trial data for grapes have been submitted and evaluated. In MRID 00053150, ethephon residues were 0.15-1.22 ppm in/on grape samples harvested 23-25 days after treatment with a single foliar application of 0.5 lb ai/A (1X). In MRID 00053153, ethephon residues were <0.01 ppm in/on six grape samples harvested 17-34 days after treatment with a single foliar application of 0.25-0.33 lb ai/A (0.5-0.7X). Ethephon residues were 0.04-0.14 ppm in/on two grape samples harvested 41 days after treatment with 0.4 lb ai/A (0.8X). In MRID 00121613, ethephon residues were 0.07-4.09 ppm in/on 61 grape samples harvested 4-49 days after treatment with a single foliar application of 0.75-4.5 lb ai/A (1.5-9X).

In another submission (MRIDs 42116501 and 42410301), ethephon residues in/on grape samples harvested 7 days after treatment with a single foliar application of 0.5 lb ai/A were <0.2-2.2 ppm. Samples harvested 10 and 14 days after treatment were <0.20-1.0 ppm and <0.2-0.69 ppm, respectively.

In a recently reviewed submission (MRID 43644302), residues of ethephon in/on grape samples harvested 7 days after a single treatment of ethephon at 0.5 lb a.i. per acre were 0.18-0.43 ppm. Residues of ethephon in/on grape samples harvested 10 and 14 days after treatment were 0.17-0.41 and 0.13-0.37 ppm, respectively.

Macadamia nuts: Adequate field trial data for macadamia nuts have been submitted and evaluated (MRID 00128726). Ethephon residues in/on 75 samples, including 12 samples treated at 1.67 lb ai/A (0.8X) were <0.01 harvested 3 and 6 days after treatment.

Peppers: Adequate field trial data for peppers have been submitted and evaluated. In a recent submission (MRID 43644303), average residues of ethephon in sweet peppers were 0.16-2.06

ppm in/on sweet peppers (from 4 field trials) harvested 5 days after application of 1 lb ai/A (1X). Average residues of ethephon were 0.52-2.37 ppm in/on hot peppers (from 6 field trials) harvested 5 days after application of 1 lb ai/A. In a previous submission (MRID 00121613), ethephon residues were 1.9-13.9 ppm in samples harvested 5 days after treatment with 1 lb ai/A, 3.1-22.4 ppm in samples harvested 7-8 days after treatment with 1 lb ai/A, and 0.3-2.64 ppm in samples harvested 12-15 days after treatment with 1 lb ai/A. In another submission (MRID 00061719), ethephon residues were <0.01-0.75 ppm in samples of fresh peppers harvested 12-15 days after aerial treatment with 1 lb ai/A, and 0.26-0.41 ppm in samples treated with 1.25 lb ai/A (1.3X). Ethephon residues were 0.42-2.9 ppm in dried peppers harvested 12-34 days after aerial application of 1 lb ai/A and 0.08-0.55 in samples from application of 0.75 lb ai/A (0.8X).

Pineapple: Adequate field trial data for pineapple have been submitted and evaluated. In a previous submission (MRID 00122452), ethephon residues were 0.02-1.05 and 0.02-0.55 ppm in/on pineapple fruit samples harvested 0-2 and 3-6 days, respectively, after treatment with a single foliar application of 0.5-1 lb ai/A (ca. 0.2-0.3X).

In another submission (MRID 42298201), twelve field trials were conducted in Hawaii where pineapples were treated under the following conditions: a) one application of ethephon at 2 lb ai/A six months prior to anticipated harvest, followed by a 1 lb ai/A treatment 2 days before harvest (1X); and b) one application of ethephon at 2 lb ai/A six months prior to harvest, followed by a 2 lb ai/A treatment 2 days before harvest. In samples harvested 1 to 2 days after the final treatment, ethephon residues in the treated pineapples ranged from 0.05 to 1.9 ppm.

Sugarcane: Adequate field trial data for sugarcane have been submitted and evaluated. In a previous submission (MRID 40954401), ethephon residues were 0.03-0.05 ppm 88 days after application of 0.5 (1X) or 1.5 lb ai/A (3X).

Tomatoes: Adequate field trial data for tomatoes have been submitted and evaluated. In a recent submission (MRID 43532401) submitted under a 6(a)(2) notification, residues of ethephon in/on tomato samples harvested 3 days after a single treatment of ethephon at 1.6 lb ai/A (1X) ranged from 0.17 to 2.24 ppm (HAFT=1.59 ppm). Residues of ethephon in/on tomato samples harvested 7 days after a single treatment of ethephon at 1.6 lb ai/A ranged from 0.04 to 1.24 ppm. Residues of ethephon in/on tomato samples harvested 10-14 days after a single treatment of ethephon at 1.6 lb ai/A ranged from 0.04 to 1.27 ppm. In a previous submission (MRID 00121613), ethephon residues were 0.05-0.51 ppm in samples harvested 1 day after treatment with 1.6 lb ai/A, 0.19-0.53 ppm in samples harvested 3 days after treatment with 1.6 lb ai/A, 0.14-1.34 ppm in samples harvested 6 days after treatment with 1.6 lb ai/A, 0.14-0.31 ppm in samples harvested 9-10 days after treatment with 1.6 lb ai/A, 0.05-1.08 ppm in samples harvested 14-15 days after treatment with 1.6 lb ai/A, and 0.12-0.42 ppm in samples harvested 18-21 days after treatment at 1.6 lb ai/A.

Walnut: Adequate field trial data for walnuts have been submitted and evaluated (MRIDs 00038795 and 00117752). In a previous submission, ethephon residues were <0.01-0.37 ppm

in/on dried walnut nutmeat samples harvested 7 days after treatment with a single foliar application of 1.25 lb ai/A (1X), <0.01-0.01 ppm in/on samples harvested 7 days after treatment with 0.75 lb ai/A (0.6X), 0.01-0.05 ppm in/on samples of undried walnuts harvested 7 days after treatment with 1.25 lb ai/A, and <0.01-0.04 ppm in/on samples of undried walnuts harvested 7 days after treatment with 0.75 lb ai/A. In another submission, ethephon residues in/on walnut nutmeats were 0.03-0.06 ppm harvested 7-36 days after treatment with 1.25 lb ai/A and <0.01-0.39 ppm in/on nutmeat samples harvested 5-20 days after treatment with 1.9-2.5 lb ai/A (1.5-2X).

Wheat: Adequate field trial data for wheat grain and straw have been submitted and evaluated. In a previous submission (MRID 00103287), ethephon residues were <0.02-0.36 ppm in/on wheat grain samples harvested 41-64 days after treatment with a single foliar application of 0.5 lb ai/A (1X). Ethephon residues were 0.04-0.46 ppm in wheat grain harvested 41-64 days after treatment with 0.75 lb ai/A (1.5X). Ethephon residues were <0.02-4.24 ppm in/on wheat straw harvested 41-64 days after treatment with 0.5 lb ai/A and <0.02-4.8 ppm in/on wheat straw harvested 41-64 days after treatment with 0.75 lb ai/A.

In another submission (MRID 42268902), ethephon residues were 0.08-0.68 ppm in/on wheat grain samples harvested 35-41 days after treatment with a single foliar application of 0.5 lb ai/A. Ethephon residues were 0.95-3.23 ppm in/on wheat straw harvested 35-41 days after treatment with 0.5 lb ai/A

A waiver was granted from the requirement for residue data on wheat hay and forage by the HED Greybeard Committee (3/1/96) because ethephon is applied after the forage/hay stage. Wheat grain dust data were previously submitted which indicated that residues of ethephon do not concentrate in aspirated wheat grain fractions. In accordance with guidance (issued June 2, 1994) on aspirated grain fractions (grain dust), additional aspirated wheat grain fractions data are not required and no tolerance is needed for residues of ethephon in/on aspirated wheat grain fractions.

7. Magnitude of the Residue in Processed Food/Feed

Adequate processing studies have been conducted on apple, barley, coffee, cottonseed, grape, pineapple, sugarcane, tomato, and wheat to determine the extent to which residues of ethephon concentrate in food/feed items upon processing of the raw agricultural commodity.

Data indicate that ethephon residues concentrate in apple juice (1.6X), barley hulls (1.6X), raisins (4.7X theoretical maximum concentration factor), grape juice (1.2X theoretical maximum concentration factor), blackstrap molasses (13.2X), wheat bran (2.5X), wheat shorts (1.8X), wheat germ (1.8X), and wheat red dog (1.2X).

Available grape processing data indicate ethephon residues concentrated in grape juice up to approximately 4X. However, the theoretical maximum concentration factor is 1.2X. No tolerance for ethephon residues in grape juice is required. Available processing data indicate that residues of ethephon do not concentrate in wet apple pomace (0.6X), refined sugar of sugarcane (0.02X), coffee roasted bean (0.6X), freeze-dried coffee (0.9X), cottonseed meal (0.7X), cottonseed oil (<0.1X), tomato juice (0.25X), tomato puree (0.44X), wheat flour (0.06X), pineapple juice (0.8X), pearled barley (0.9X), wheat aspirated grain fractions (0.6X) and tomato paste (0.55X). Therefore, no tolerances are required.

The Agency no longer considers pineapple bran a processed commodity of pineapple, but now considers pineapple juice and the wet waste byproduct from fresh-cut product line, referred to as pineapple process residue, as the processed commodities of pineapple. Pineapple processing data indicate that residues of ethephon concentrate in dried pineapple bran (5.3x) and wet pulp (1.2x) but do not concentrate in juice, syrup, and slices. Based on these data which demonstrate that there is no significant concentration of residues of ethephon in pineapple wet pulp (1.2x), the Agency concludes that no tolerance for residues of ethephon in pineapple process residue is required.

8. Magnitude of the Residue in MMPE

Ruminants (MRID 44100201)

Holstein dairy cows were dosed daily with ethephon at levels of 0, 43, 129, and 430 ppm in the diet. Each treatment group had three cows. Milk samples were taken on days 1, 4, 8, 11, 15, 18, 22, 25, and 27. The cows were sacrificed on day 28 and samples stored frozen for <30 days prior to analysis. Samples of milk and tissues were analyzed with the ethylene release method. The concurrent method validation data were reported above. The maximum residues observed in milk and tissues are shown in Table 4. At the 43 ppm dietary burden, quantifiable residues were observed in milk (0.0074 ppm), liver (0.095 ppm), muscle (0.016 ppm), and kidney (0.638 ppm).

Table 4- Maximum ethephon residues (ppm) in dairy cattle after 28 days of dosing at a rate of 43, 129 and 430 ppm.

Fraction	Dose Level		
	43 ppm	129 ppm	430 ppm
Milk	0.0074*	0.0186 [#]	0.0331*
Liver	0.095	0.646	1.503

Kidney	0.638	3.509	10.918
Fat	<0.01	0.069	0.127
Muscle	0.016	0.061	0.170

*Day 1 sample, #Day 4 sample.

The maximum dietary burden in dairy cows from the proposed and established uses of ethephon results from a diet comprised of cotton and wheat commodities:

Table 5. Maximum dietary burden for dairy cattle.

Feed Item	% Diet	Tolerance (ppm)	% DM	ppm in Diet
Cotton gin byproducts	20	180	90	40.0
Cottonseed	25	6.0	88	1.7
Cottonseed meal	15	6.0*	89	1.0
Cottonseed hulls	15	6.0*	90	1.0
Wheat straw	20	10	88	2.3
Wheat milled byproducts	5	5.0	88	0.3
Total	100			46.3

*Covered by RAC tolerance

The maximum dietary burden in beef cows from the proposed and established uses of ethephon results from a diet comprised of cotton and wheat commodities:

Table 6. Maximum dietary burden for beef cattle.

Feed Item	% Diet	Tolerance (ppm)	% DM	ppm in Diet
Cotton gin byproducts	20	180	90	40.0
Cottonseed	25	6.0	88	1.7
Cottonseed meal	15	6.0*	89	1.0
Cottonseed hulls	20	6.0*	90	1.3
Wheat straw	10	10	88	1.1
Wheat milled byproducts	10	5.0	88	0.6
Total	100			45.7

*Covered by RAC tolerance

Based on the estimated maximum dietary burden of 46 ppm, the dietary feeding levels in this study were 0.9X, 2.7X, and 9X. The results of this feeding study indicate that the appropriate tolerances are:

Milk -- 0.01 ppm | Kidney* -- 1.0 ppm
 Meat* -- 0.02 ppm | Fat* -- 0.02 ppm
 Meat Byproducts (except kidney)* -- 0.20 ppm

*of cattle, goat, hogs, horses and sheep

The currently established ethephon meat and milk tolerances of 0.1 ppm are thus inadequate to support the proposed use on cottonseed (PP#6F4743). The registrant has submitted a revised Section F with the appropriate milk and ruminant tissue tolerances (T. Morton, D280983, 5/7/02).

Poultry (MRID 44100202)

Leghorn laying hens were dosed daily with ethephon at levels of 0, 2.3, 6.9, and 23 ppm in the diet. Each group had 10 hens. Egg samples were taken on days 1, 4, 8, 11, 15, 18, 22, 25, and 27. The animals were sacrificed on day 28 and samples stored frozen for <30 days prior to analysis. Samples of eggs and tissues were analyzed with the ethylene release method. The concurrent method validation data were reported above. The maximum residues observed in eggs and tissues are shown in Table 7. At the 2.3 ppm dose level, quantifiable residues were observed in liver (0.033 ppm) and skin/fat (0.014 ppm).

Table 7. Maximum ethephon residues (ppm) in laying hens after 28 days of dosing at a rate of 2.3, 6.9 and 23 ppm.

Fraction	Dose Level		
	2.3 ppm	6.9 ppm	23 ppm
Eggs	NA	NA	0.0036*
Skin + Fat	0.014	0.032	0.117
Liver	0.033	0.068	0.289
Muscle	<0.010	0.015	0.060

NA = Not analyzed, *Day 8

The maximum dietary burden in poultry from the proposed and established uses of ethephon results from a diet comprised of cotton and wheat commodities:

Table 8. Maximum dietary burden in poultry.

Feed Item	% Diet	Tolerance (ppm)	ppm in Diet
Cottonseed meal	20	6.0*	1.2
Wheat milled byproducts	50	5.0	2.5
Wheat grain	30	2.0	0.6
Total	100		4.3

*Covered by RAC tolerance

Based on the estimated maximum dietary burden of 4.3 ppm, the dietary feeding levels in this

study were 0.5X, 1.6X, and 5.3X. The results of this feeding study indicate that the appropriate tolerances are:

Eggs	--	0.002 ppm	Poultry Liver	--	0.05 ppm
Poultry Meat	--	0.01 ppm	Poultry Fat	--	0.02 ppm
Poultry Meat Byproducts (except liver)	--	0.01 ppm			

There are currently no established tolerances for residues of ethephon on poultry RACs. The registrant has submitted a revised Section F with the appropriate egg and poultry tissue tolerances (T. Morton, 5/7/02, D280983).

9. Submittal of Analytical Reference Standards

Analytical reference standards must be supplied as requested by the EPA National Pesticide Standards Repository for ethephon.

10. Confined and Field Accumulation in Rotational Crops

The registrant has submitted a confined rotational crop study (B. Cropp-Kohlligian, D200239, 3/27/95) which was deemed adequate in a recent review (T. Morton, D280663, 5/9/02). Radioactive residues in collards, radishes, and wheat commodities were adequately characterized. The majority of the radioactivity (50-85% of TRR) in all matrices was characterized as bound and was subsequently fractionated into putative natural constituents. Derivatization and mass spectral analysis of putative cellulose fractions indicated that ¹⁴C-residues were incorporated into plant biomolecules. Extractable radioactive residues (hexane/EtOAc/MeOH combined soxhlet extracts) of radish, collard, and wheat commodities ranged from 0.023-0.074 ppm (above the 0.01 ppm trigger value; representing 9-38% of TRR) at the 30-day plant-back interval and 0.017-0.050 ppm (above the 0.01 ppm trigger value; representing 19-49% of TRR) at the 120-day plant-back interval. Radioactive residues in the hexane/EtOAc/MeOH combined soxhlet extracts were ≤ 0.010 ppm (below the 0.01 ppm trigger value) in all commodities at the 379-day plant-back interval. Unidentified bound radioactive residues in samples from the 30- and 120-day plant-back intervals accounted for 4-34% of the TRR. Based on the results of the confined rotational crop study, plant-back label restrictions for ethephon containing end-use products are not required.

E. TOLERANCE REASSESSMENT SUMMARY

Tolerances Listed Under 40 CFR §180.300(a)

The tolerances listed in 40 CFR §180.300(a) are for residues of ethephon *per se*.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.300(a) for the following commodities: apples; barley grain and straw; blackberries; blueberries, cherries; grape, raisin; Macadamia nuts; pineapples; tissues and milk of cattle, goat,

hog, horses, and sheep; tomatoes; walnuts; wheat, milling fractions, except flour; and wheat grain and straw. Sufficient data are available to assess residue levels of ethephon in tobacco.

The established tolerance of 2 ppm for residues of ethephon in/on cottonseed should be increased to 6.0 ppm. The registrant has amended PP#6F4743 to propose an increase in the currently established tolerance level for residues of ethephon in/on cottonseed from 2 ppm to 6 ppm and also proposed a tolerance of 180 ppm for ethephon in cotton gin byproducts (PP#6F4743, T. Morton, D280983, 5/7/02).

Pending the further amendment of the 0.33 lb/gal SC/L product label (EPA Reg. No. 264-263 dated 8/11/94) to prohibit the harvesting of any treated pumpkins for human or animal consumption and specify that treatments are to be made to pumpkins for seed production only, the Agency has hereby concluded that currently registered use of ethephon on cucumbers, squash, and pumpkins for hybrid seed production is a non-food use and the 0.1 ppm tolerances for cucumbers and pumpkins should be revoked. [Note: No tolerance is established for residues of ethephon in/on squash.]

Cranberries and figs have been deleted from ethephon product labels. Tolerances for residues in/on these commodities should be revoked.

Tolerances for fat and meat of cattle, goat, hog, horse, and sheep can be reduced from 0.1 ppm to 0.02 ppm. The tolerances for mbyp of cattle, goat, hog, horse, and sheep should be revoked and new tolerances for meat byproducts, except kidney needs to be established for cattle, goat, hog, horse, and sheep. An increase in tolerances for meat byproducts of cattle, goat, hog, horse, and sheep from 0.1 ppm to 0.20 ppm is required. The tolerance for milk can be reduced from 0.1 ppm to 0.01 ppm. No tolerances for residues of ethephon in poultry tissues or eggs have been established. Tolerances for egg and poultry tissues have been proposed by the registrant and accepted by HED (T. Morton, 5/9/02, D280983).

IR-4 has proposed an increase in the tolerance of 0.1 ppm for coffee, bean to 0.50 ppm. This petition is being reviewed concurrently with this update of the chemistry chapter.

A summary of the ethephon tolerance reassessment and modifications in commodity definitions are presented in Table 9.

Tolerances Listed Under 40 CFR §180.300(b)

The tolerance listed in 40 CFR §180.300(b) is with a regional registration as defined in 180.1(n) for residues of ethephon *per se* in/on sugarcane. Sufficient data are available to ascertain the adequacy of this established tolerance.

New Tolerances

Tolerances have been proposed for the following commodity: apple juice (10 ppm).

The Agency currently recognizes cotton gin byproducts as a raw agricultural commodity. The registrant has proposed a tolerance of 180 ppm for ethephon residues in/on cotton gin byproducts (PP#6F4743, T. Morton, D280983, 5/9/02).

A tolerance of 1.0 ppm needs to be established for kidney of cattle, goat, hog, horse, and sheep.

1. Tolerance Reassessment Table

Table 9. Tolerance Reassessment Summary for Ethephon.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR §180.300 (a)			
Apple	5.0	5.0	<i>Apple</i>
Barley, bran	5.0	5.0	
Barley, grain	2.0	2.0	
Barley, pearled barley	5.0	Revoke	Tolerance for barley, grain will cover barley, pearled barley.
Barley, straw	10.0	10	
Blackberry	30.0	30	<i>Blackberry</i>
Blueberry	20.0	20	<i>Blueberry</i>
Cantaloupe	2.0	2.0	<i>Cantaloupe</i>
Cattle, fat	0.1	0.02	Tolerance can be reduced.
Cattle, mbyp	0.1	Revoke	Separate tolerances for <i>Cattle, meat byproducts, except kidney</i> and <i>Cattle, kidney</i> need to be established.
Cattle, meat	0.1	0.02	Tolerance can be reduced.
Cherry	10	10	<i>Cherry</i>
Coffee, bean	0.1	0.50	Increase in tolerance required./ <i>Coffee, green bean</i>
Cottonseed	2	6.0	Increase in tolerance required./ <i>Cotton, undelinted seed</i>
Cranberry	5	Revoke	No registered uses exist.
Cucumber	0.1	Revoke	Registrant limiting use to cucumbers grown solely for seed.
Fig	5	Revoke	No registered uses exist.
Goat, fat	0.1	0.02	Tolerance can be reduced.
Goats, mbyp	0.1	Revoke	Separate tolerances for <i>Goat, meat byproducts, except kidney</i> and <i>Goat, kidney</i> need to be established.
Goat, meat	0.1	0.02	Tolerance can be reduced./ <i>Goat, meat</i>
Grape	2.0	2.0	<i>Grape</i>
Hog, fat	0.1	0.02	Tolerance can be reduced./ <i>Hog, fat</i>
Hog, mbyp	0.1	Revoke	Separate tolerances for <i>Hog, meat byproducts, except kidney</i> and <i>Hog, kidney</i> need to be established.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Hog, meat	0.1	0.02	Tolerance can be reduced./ <i>Hog, meat</i>
Horse, fat	0.1	0.02	Tolerance can be reduced./ <i>Horse, fat</i>
Horse, mbyp	0.1	Revoke	Separate tolerances for <i>Horse, meat byproducts, except kidney</i> and <i>Horse, kidney</i> need to be established.
Horse, meat	0.1	0.02	Tolerance can be reduced.
Nut, macadamia	0.5	0.50	
Milk	0.1	0.01	Tolerance can be reduced.
Pepper	30	30	<i>Pepper</i>
Pineapple	2	2.0	
Pumpkin	0.1	Revoke	Use limited to pumpkins grown solely for seed.
Raisin	12	12	<i>Grape, raisin</i>
Sheep, fat	0.1	0.02	Tolerance can be reduced.
Sheep, mbyp	0.1	Revoke	Separate tolerances for <i>Sheep, meat byproducts, except kidney</i> and <i>Sheep, kidney</i> need to be established.
Sheep, meat	0.1	0.02	Tolerance can be reduced.
Sugarcane, molasses	1.5	1.5	
Tomato	2	2.0	
Walnut	0.5	0.50	<i>Walnut</i>
Wheat, bran	5.0	5.0	
Wheat, grain	2.0	2.0	
Wheat, milled fractions (exc. flour)	5.0	5.0	<i>Wheat, milled byproducts</i>
Wheat, straw	10.0	10	
Tolerances listed under 40 CFR §180.300(b)			
Sugarcane	0.1	0.10	Regional registration (HI only).
Tolerances to be proposed under 40 CFR §180.300 (a)			
Apple, juice	N/A	10	New tolerance needed.
Cotton, gin byproducts	None	180	New tolerance needed.
Egg	None	0.002	New tolerance needed.
Cattle, kidney	None	1.0	New tolerance needed.
Cattle, meat byproducts, except kidney	None	0.20	New tolerance needed.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Goat, kidney	None	1.0	New tolerance needed.
Goat, meat byproducts, except kidney	None	0.20	New tolerance needed.
Hog, kidney	None	1.0	New tolerance needed.
Hog, meat byproducts, except kidney	None	0.20	New tolerance needed.
Horse, kidney	None	1.0	New tolerance needed.
Horse, meat byproducts, except kidney	None	0.20	New tolerance needed.
Sheep, kidney	None	1.0	New tolerance needed.
Sheep, meat byproducts, except kidney	None	0.20	New tolerance needed.
Poultry, fat	None	0.02	New tolerance needed.
Poultry, liver	None	0.05	New tolerance needed.
Poultry, meat	None	0.01	New tolerance needed.
Poultry, meat byproducts, except liver	None	0.01	New tolerance needed. A previous memo (D280983, 5/7/02, T. Morton) incorrectly stated the registrant proposed a tolerance for Poultry, meat byproducts, except kidney.
Wheat, germ	None	5.0	New tolerance needed.
Wheat, shorts	None	5.0	New tolerance needed.

2. Codex Harmonization

Several maximum residue limits (MRLs) for ethephon have been established by Codex. Both Codex and the U.S. regulate ethephon *per se*. The Codex MRLs, applicable U.S. tolerances, and recommendations for harmonizing U.S. tolerances with Codex MRLs are presented in Table 10.

Table 10. Codex MRLs and applicable U.S. tolerances. Recommendations for compatibility are based on conclusions following reassessment of U.S. tolerances (see Table 9).

Commodity	MRL (mg/kg) ¹	U.S. Reassessed Tolerance (ppm)	Recommendation
Apple	5	5.0	Compatibility exists.
Barley	1	2.0	
Barley straw and fodder, dry	5	10	
Blueberry	20	20	Compatibility exists.
Cantaloupe	1 (step 6)	2.0	
Cherry	10	10	Compatibility exists.
Cottonseed	2	6.0	
Edible offal of cattle, goats, horses, pigs, and sheep	0.2	2.0	U.S. kidney tolerance is 2.0 ppm and meat byproducts tolerance is 0.20 ppm.
Egg	0.2	0.002	
Fig, dried or dried and candied	10	5	U.S. tolerance to be revoked; no registered uses.
Grape	1 (step 6)	2	
Hazelnut	0.2	None	
Meat of cattle, goats, horses, pigs, and sheep	0.1	2	
Milk of cattle, goats, and sheep	0.05	0.01	
Pepper	5 (step 6)	30	
Pineapple	2	2	Compatibility exists.
Poultry meat	0.1	0.01	
Poultry, edible offal of	0.2	0.02	
Rye	1	None	
Rye straw and fodder, dry	5	None	
Tomato	2	2.0	Compatibility exists.
Walnut	0.5	0.5	Compatibility exists.
Wheat	1	2.0	
Wheat straw and fodder, dry	5	10	

¹ All ethephon MRLs are Step 4.

The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs:

- Compatibility between the U.S. tolerances and Codex MRLS exists for apples, blackberries, cherries, pineapples, and walnuts.
- The guideline level for ethephon residues in/on tomatoes (3 ppm) is higher than the established U.S. tolerance (2 ppm). Should the Codex Committee adopt this recommendation, compatibility could be achieved by increasing the U.S. tolerance to 3 ppm.
- No questions of compatibility exist with respect to commodities where: (i) no Codex MRLs have been established but U.S. tolerances exist; or (ii) Codex MRLs have been established but U.S. tolerances do not exist.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

Date	DP Barcode	CB No.	From	To	MRID Nos.	Subject
5/24/88	None	None	D. Edwards	R. Taylor/A. Rispin	None	Addendum to the Residue Chemistry Chapter of the Ethephon Registration Standard - Additional Data Requirements for Monochloroacetic Acid
8/7/90	None	6472, 6473, and 6474	S. Funk	R. Taylor/A. Barnes	None	Temporary Tolerance Request and EUP Request for Ethephon
11/2/90	None	7167	W. Smith	C. Peterson	41296201	Ethephon Registration: Multiresidue Testing Data Requirements
9/5/91	D165461	8135	L. Cheng	C. Giles-Parker	None	EPA Reg. No. 264-267. Ethephon Amended Use Apples
9/26/91	D164042	7936	B. Cropp-Kohlligian	R. Taylor	41872501	EPA Reg. No. 264-267. Amended Use Request for Ethrel
9/27/91	D165460	8136	B. Cropp-Kohlligian	C. Giles-Parker	41872501	EPA Reg. No. 264-267. Amended Use Request for Ethrel
11/25/91	D159333	7476	R. Lascola	R. Taylor/E. Allen	41704501	FAP#1H5603: Response to Data Call-In: Ethephon (Prep) In and/or On RAC Cottonseed (Amendment of Existing Tolerance) and Processed Cottonseed Commodities, Refined Oil, Meal, and Soapstock (New Food/Feed Additive Tolerances)
1/9/92	D161111	7678	F. Toghrol	L. Rossi/C. Peterson	41746501	Ethephon on Tobacco, Pyrolysis Study. Rhone Poulenc: Response to the Ethephon Registration Standard Residue Chemistry Data Requirements
2/12/92	D172474	9113	B. Cropp-Kohlligian	C. Giles-Parker	42116501	EPA Reg. No. 264-267. Registrant's Responses to CBRS's Conclusions and Recommendations Concerning the Amended Use Requests for Ethrel

3/31/92	D169084	8635	P. Deschamp	C. Peterson	42016701	Reregistration of Ethephon. Tomato Field Trials and Processing Studies
4/1/92	D168467	8564	P. Deschamp	L. Rossi/C. Peterson	41872502	Reregistration of Ethephon. Apple Processing Study
4/4/92	D168968	8267	P. Deschamp	L. Rossi/C. Peterson	42010401	Reregistration of Ethephon. Storage Stability Data for Walnuts
8/7/92	D171074	8920	R. Lascola	J. Kariya/C. Lewis/C. Giles-Parker	None	Ethephon (Ethrel) on Sugarcane. Anticipated Residues for Food and Animal Commodities
9/8/92	D180648	10246	D. McNeilly	L. Propst	42379101	Reregistration of Ethephon. Review of Chromatograms of Whole Apples and Apple Processed Commodities
9/16/92	D176113	9610	B. Cropp-Kohlligian	L. Rossi	42236701	Ethephon Poultry Metabolism Review
10/27/92	D178357	9887	B. Cropp-Kohlligian	L. Rossi	42268904 through 42268909, 42300801 through 42300808, 42268902, 42268903, 42298201, and 42268901	Reregistration of Ethephon. Storage Stability Data, Residue Data on Wheat Grain and Straw, Tomatoes, and Pineapple, As Well As Wheat Grain Processing Data and Pineapple Processing Data
1/19/93	D180648	10246	D. McNeilly	L. Propst	None	Addendum to CBRS 10246; MRID: 423791-01; DP Barcode: 180648
2/16/93	D182586	10585	A. Aikens	L. Propst	42464401	Ethephon: Rhone-Poulenc Response to the Reregistration Standard Update Dated 4/91 Residue Chemistry Field Trial for Walnuts
2/22/93	None	None	B. Cropp-Kohlligian	CBRS Files	None	Meeting with Representatives of Rhone-Poulenc to Discuss Reregistration of Ethephon
3/25/93	D188776	11493	P. Deschamp	J. Loranger	None	Reregistration of Ethephon. Comments on Rhone-Poulenc's Letter Dated February 1, 1993

3/30/93	D181311	10341	P. Deschamp	J. Loranger	42410401, 02, and 03	Reregistration of Ethephon. Final Storage Stability Reports on Wheat Grain, Wheat Straw, and Cottonseed
4/15/93	D187910	11344	P. Deschamp	C. Giles-Parker	None	Reregistration of Ethephon. Amended Section F (FAP#1H5603). Proposed Food/Feed Additive Tolerance for Cottonseed Meal
4/20/93	D188033	11357	P. Deschamp	C. Giles-Parker	None	Reregistration of Ethephon. Proposed Food/Feed Additive Tolerances for Apple Pomace, Apple Juice, Tomato Pomace, Pineapple Bran, Grape Juice, Raisins, and Dried Grape Pomace
5/5/93	D188852	11479	J. Miller	J. Loranger	42381701	CBRS Response to Registrant Request to Upgrade Sugarcane Processing Study for Ethephon
5/10/93	D190075	11681	P. Deschamp	J. Loranger	42718101	Reregistration of Ethephon. Storage Stability in Cantaloupe and Other Issues (Rotational Crop Time Extension, Cucumbers Proposed Label Amendment, Storage Stability Data Waivers)
9/22/93	D188672	11467	B. Cropp-Kohlligian	L. Rossi	42410301	Review of Grape/Raisin Waste Chromatograms and Analytical Conduct Information to Support Previously Submitted Grape/Raisin Waste Data
12/20/93	D182143	10510	G. Kramer	C. Giles-Parker	42410301 and 02	Label Amendment for Use on Grapes
1/26/94	D207953 and D207947	14459 and 14460	G. Kramer	C. Giles-Parker/A. Kocialski	433684202 through -12, -55, -56, -58, -59, and 43379803	PP#4G4414. New Chemical - Cyclanilide Sodium in/on Cotton. Evaluation of Residue Data and Analytical Methods
2/8/94	D188081 and D192479	11366 and 12084	P. Deschamp	J. Loranger	None	Reregistration of Ethephon. Magnitude of the Residue Data for Cantaloupes. Storage Stability Data for Processed Fractions

2/8/94	D192207	12013	P. Deschamp	L. Rossi/J. Loranger	None	Reregistration of Ethephon. Data Requirements Clarification: Tobacco, Barley, and Cottonseed
2/10/94	D192265 and D192479	12034 and 12084	P. Deschamp	J. Loranger	None	Reregistration of Ethephon. Magnitude of the Residue Data for Cantaloupes. Storage Stability Data for Processed Fractions
2/28/94	D196180	12722	P. Deschamp	L. Rossi/J. Loranger	None	Reregistration of Ethephon. Registrant's Response to Storage Stability Data Requirements (Rhone-Poulenc Letter dated 3/29/93)
6/27/94	D195976 and D196179	12698 and 12727	B. Cropp-Kohlligian	L. Propst	42957301 and 42957302	Ethephon Reregistration. New Proposed Plant and Animal Enforcement Methods and Meat, Milk, and Egg Storage Stability Data and Further Evaluation of Previously Submitted Meat, Milk, Poultry, and Egg Magnitude of the Residue Data
8/18/94	D203759	13779	B. Cropp-Kohlligian	L. Propst/J. Loranger	None	Ethephon Reregistration. Registrant's Response to Storage Stability Data Requirements (Rhone-Poulenc Letter dated 5/12/94)
10/26/94	D208299	14511	S.. Willett	C. Giles-Parker	None	HI-940004. 24c (SLN) Registration of Ethephon on Pineapples in Hawaii
1/23/95	None	None	B. Cropp-Kohlligian	HED Metabolism Committee	None	Ethephon Reregistration. Issue to be presented at the 1/30/95 meeting of the HED Metabolism Committee
2/10/95	None	None	B. Cropp-Kohlligian	HED Metabolism Committee	None	Ethephon Reregistration. Outcome of the 1/30/95 Meeting of the HED Metabolism Committee
3/29/95	None	None	B. Cropp-Kohlligian	J. Loranger	00123222 (previously submitted/reviewed)	Ethephon Reregistration. Special Local Needs (SLN) registration of ethephon on Spur Red Delicious apples in North Carolina (SLN No. NC-820007)

3/29/95	D200239	13330	B. Cropp-Kohlligian	L. Propst	43143601	Ethephon Reregistration. Confined Rotational Crop Study
6/1/95	D214823	15543	G. Kramer	C. Giles-Parker/J. Smith	None	PP#4G4414. New Chemical - Cyclanilide Sodium in/on Cotton. Amendment Of 4/24/95
5/15/96	D224555	17076	G. Kramer	J. Smith/D. McCall	43876601, 43868201 through -06, 43868301, -32, -35 through -43, and 43878101	PP#6F04643. Cyclanilide in/on Cottonseed and Animal RACs. Evaluation of Residue Data and Analytical Methods
8/5/96	D227931	17376	G. Kramer	J. Smith/D. McCall	None	PP#6F04643. Cyclanilide in/on Cottonseed and Animal RACs. Amendment of 6/25/96
10/29/96	D227554, D227555, D230176, & D230177	17353 & 17354	G. Kramer	D. Davis	44100201, 44100202, and 44100203	PP#6F04743 & FAP#1H05603. Ethephon in/on Cotton. Evaluation of Residue Data and Analytical Methods
4/2/98	D239736	None	J. Punzi	J. Loranger	44382801	Ethephon Reregistration. Interregional Research Project No. 4 (IR-4) Blueberry Storage Stability Study
5/8/98	D224690	None	W. Wassell	C. Giles-Parker	None	ID# 000264-00257; Ethephon in/on pineapple. Request for Amended Use Pattern
2/21/02	D211170 & D222792	14996 & 16868	T. Morton	J. Bazuin/T. Northern	43514701	Nature of the Residue in Livestock - Poultry Metabolism Study
2/21/02	D227485 & D227938	None	T. Morton	J. Bazuin/T. Northern	44036001	Radiovalidation of the Livestock Enforcement Method
2/26/02	D280665	None	T. Morton	J. Bazuin/T. Northern	43660201	Magnitude of the Residue in/on Cantaloupe
2/26/02	D280667	None	T. Morton	J. Bazuin/T. Northern	43532401	Magnitude of the Residue in/on Tomato Submitted Under a 6(a)(2) Notification

2/26/02	D280668	None	T. Morton	J. Bazuin/T. Northern	43644301, 43644302, and 43644303	Storage Stability in Processed Commodities, Magnitude of the Residue in/on Grapes, and Magnitude of the Residue in/on Peppers
4/16/02	D221159	16515	T. Morton	J. Bazuin/T. Northern	43842101	Registrant's Response to Deficiencies for Storage Stability in Sugarcane
4/16/02	D282427	None	T. Morton	J. Bazuin/T. Northern	4386834 (previously reviewed)	Ethephon. Waiver Request for Magnitude of Residue in Cotton Gin Byproducts
5/2/02	D280666	None	T. Morton	J. Bazuin/T. Northern	43663601	Response to Deficiencies: Submission of Independent Laboratory Validation (ILV)
5/7/02	D280983	None	T. Morton	J. Bazuin/T. Northern	None	PP#6F4743. Ethephon (099801): Ethephon in/on Cottonseed: Revised Sections F and G
5/9/02	D280663	None	T. Morton	J. Bazuin/T. Northern	43725101	Ethephon: Response to Deficiencies; Submission of HPLC Chromatograms to Upgrade the Previously Submitted Confined Rotational Crop Study
5/28/02	D282695	None	T. Morton	R. Daiss/ C. Olinger/J. Bazuin/T. Northern	None	Minutes of the HED Ethephon Risk Assessment Team Meeting of 4/25/02 discussing the hydroxy metabolite in water and poultry metabolism studies
6/18/02	D280664	None	T. Morton	J. Bazuin/T. Northern	43738801 and 43738802	Ethephon. Test Sample Storage Information for Grape Commodities and Magnitude Ethephon Residues in Sugarcane Processed Commodities
6/20/02	D283033	None	T. Morton	R. Daiss/J. Bazuin/T. Northern	45195801	PP#0E6205. Ethephon (099801): Ethephon in/on Coffee

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- 00032573 Harrison, S.L. Nygren, R.E. Gross, S.M. et al. (1980) Residues: Ethrel (R)/Sugarcane: Project No. 10223. Unpublished study received May 15, 1980, under 264-EX-59; prepared in cooperation with Hawaiian Sugar Planter's Association, submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:099427-A.
- 00036500 Obenauf, G.L. (1973) Residues: [Ethephon]. (Unpublished study received Mar 19, 1974 under 4F1490; prepared in cooperation with Greenwood Laboratories, Inc., submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:093944-B)
- 00038793 Union Carbide Agricultural Products Company (1972) Metabolism: The Nature and Quantities of Residues and Metabolic Degradation Products Resulting from the Treatment of Walnuts with Ethephon. (Unpublished study received Dec 20, 1972 under 3F1344; CDL:093599-C)
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- 00038797 Lagerstedt, H. (1972) Residues: [Ethephon]. (Unpublished study received Dec 20, 1972 under 3F1344; prepared in cooperation with Oregon State Univ., submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:093599-G)
- 00038880 Amchem Products, Incorporated (1972) Detailed Method of Analysis for Residues of (2-Chloroethyl)phosphonic acid (Ethephon) in Walnuts. Method dated Nov 1972. (Unpublished study received Dec 20, 1972 under 3F1344; submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:093596-A)
- 00038881 Amchem Products, Incorporated (1972) Detailed Method of Analysis for Residues of (2-Chloroethyl)phosphonic acid (Ethephon) in Filberts. Method dated Nov 1972. (Unpublished study received Dec 20, 1972 under 3F1344; submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:093596-B)
- 00040268 Union Carbide Agricultural Products Company (19??) Effect of Temperature on the Level of Ethephon Residue in Pineapple Shell. (Unpublished study received Aug 27, 1971 under 2G1195; CDL:095928-A)
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- 00042977 Union Carbide Agricultural Products Company (19??) Analysis of Pineapple Tissue for Residues of 2-Chloroethylphosphonic acid. Undated method. (Unpublished study received Dec 23, 1969 under 264-257; CDL:100700-D)

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